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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/964,178	09/25/2001	Robert Raffa	TUN-566US	9598

7590 02/13/2003

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EXAMINER

FONDA, KATHLEEN KAHLER

ART UNIT PAPER NUMBER

1623

DATE MAILED: 02/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/964,178

Applicant(s)

RAFFA ET AL.

Examiner

Kathleen Kahler Fonda, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 December 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 September 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2. 6) ☐ Other: _____

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Claim 1 is objected to as informal because it appears that --than-- should be inserted after "greater" in line 4. Claim 16 is objected to as informal because it appears that --01:2-- should be replaced with "1:2" in line 6. Correction of these apparent typographical errors is requested.

Applicant is advised that should claim 1 be found allowable, claim 13 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Claim 1 and claim 13 are substantial duplicates because claim 13 does not require any ingredient other than the dosage form of claim 1.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use

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or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-5 and 7-16 are rejected under 35 U.S.C. 102(e) as being anticipated by PETRUS (A). Example 1 of PETRUS teaches a dosage form comprising glucosamine sulfate and ibuprofen, wherein the weight ratio of glucosamine sulfate to ibuprofen is 4:1. Ibuprofen is an NSAID and a propionic acid analgesic. Example 5 of PETRUS teaches administration of the dosage form of Example 1 to a human patient suffering from rheumatoid arthritis, for relief of pain. Dosage amounts of instant claim 15 are taught by PETRUS at column 11, lines 34-38. Additional ingredients within the scope of those recited in instant claim 12 are also included in the dosage form of Example 1. Thus the claims are anticipated.

It is not relevant to the anticipation analysis that PETRUS may not discuss synergistic effects. It would appear that Applicant has at best discovered a new benefit of a composition

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and process for using it which both are old. The court in *In re Woodruff* (16 USPQ2d 1934, 1936 (CAFC 1990)) stated, "It is a general rule that merely discovering and claiming a new benefit of an old process cannot render the process again patentable."

Claims 1-4, 6, 7, 12, and 13 are rejected under 35 U.S.C. 102(e) as being anticipated by GIORGETTI (B). The Examples of GIORGETTI show glucosamine salts of ketoprofen which meet the limitations of claim 6. Additional ingredients within the scope of those recited in instant claim 12 are also included in the dosage forms of the Examples. Because there is no reduction in the anti-inflammatory effect of the salt as compared to the ketoprofen free acid (see Table 1), it is reasonable to conclude that the analgesic effect is also undiminished. Furthermore, column 4, lines 66-67 states, "Investigations in experimental animals evidenced a surprising increase in anti-inflammatory and analgesic activity."

Claims 1-5, 7, and 13-15 are rejected under 35 U.S.C. 102(b) as being anticipated by PARADIES (AH). Example 2 of PARADIES teaches a salt of ibuprofen and a glucosamine. Because the salt of PARADIES contains two ingredients known to be useful for pain relief (glucosamine and ibuprofen), one

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ordinarily skilled in the art would expect the analgesic efficiency to be enhanced over ibuprofen alone, as required by claim 2. Reference claims 8-12 teach administration of amounts within the scope of claim 15 to a subject suffering from pain, which is understood in context to mean a human subject. Thus the claims are anticipated.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in

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order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over PETRUS.

Applicant claims a dosage form comprising glucosamine and ketoprofen, such that the analgesic efficiency of the dosage form is equal to or greater than that of the ketoprofen alone at the same dosage level.

PETRUS teaches as set forth above. PETRUS also teaches that ketoprofen is a known NSAID, useful for relieving inflammation, pain, and swelling; see column 4, lines 10-55.

It would have been obvious for a person of ordinary skill in the art at the time of the invention to substitute ketoprofen for ibuprofen in the composition taught by PETRUS in Example 1. An ordinarily skilled artisan would have been motivated to do so with a reasonable expectation of success, because both ketoprofen and ibuprofen were known to be members of the same class of NSAID drugs, and both were known to be useful for pain management. Furthermore, since both are propionic acid analgesics, one of ordinary skill would reasonably have expected ketoprofen to be substitutable for ibuprofen in the dosage form such that the analgesic efficiency of the ketoprofen in the

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dosage form would not be diminished as compared to the that of the ketoprofen alone at the same dosage level. There would have been no expectation of any chemical reaction that might interfere with the efficacy of the ketoprofen.

Claims 1, 2, 14, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over GIORGETTI (B).

Applicant claims a method to alleviate pain in a human subject by administering a dosage form comprising glucosamine and ketoprofen, such that the analgesic efficiency of the dosage form is equal to or greater than that of the ketoprofen alone at the same dosage level.

GIORGETTI teaches as set forth above. GIORGETTI also teaches in claim 43 that the salts may be administered to mammals. GIORGETTI does not explicitly teach administration to a human.

It would have been obvious for a person of ordinary skill in the art at the time of the invention to administer the salt of GIORGETTI to a human. There would have been a reasonable expectation of success because a human is a mammal, and ketoprofen itself was well-known for human use.

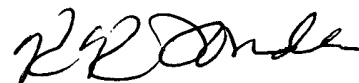
No claim is allowed.

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Papers relating to this application may be submitted to Technology Center 1600 by facsimile transmission. The number of the fax machine for official papers in Technology Center 1600 is (703) 308-4556. Any document submitted by facsimile transmission will be considered an official communication unless the cover sheet clearly indicates that it is an informal communication.

INTERNET INFORMATION: Secure and confidential access to patent application status information is now available; see <http://www.uspto.gov/ebc/index.html> for more information. Also, <http://www.uspto.gov/web/offices/ac/comp/fin/clonedefault.htm> may be used to pay patent maintenance fees, pay non-filing application fees, and maintain USPTO deposit accounts.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Kathleen Kahler Fonda, at telephone number (703) 308-1620. Examiner Fonda can generally be reached Monday through Friday from 7:30 a.m. until 4:00 p.m. If the Examiner cannot be reached, questions may be addressed to Supervisory Patent Examiner James O. Wilson at (703) 308-4624. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-1235.


KATHLEEN K. FONDA
PRIMARY EXAMINER